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Health Advisory: CDC and FDA Alert for Healthcare Facilities to Immediately Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices – 11 September 2015

Action requested:

- Healthcare facilities (e.g., hospitals, ambulatory surgical centers, clinics and doctors' offices) that utilize reusable medical devices are urged to immediately review current reprocessing practices at their facility to ensure they are 1) complying with all steps recommended by the device manufacturers and 2) have in place appropriate policies and procedures that are consistent with current standards and guidelines.
- Healthcare facilities should arrange for a healthcare professional with expertise in device reprocessing to immediately assess their reprocessing procedures. This assessment should ensure that reprocessing is done correctly, including allowing enough time for reprocessing personnel to follow all steps recommended by the device manufacturer.
- Review the complete CDC Alert and recommendations at, http://emergency.cdc.gov/han/

Background: Recent infection control lapses due to non-compliance with recommended reprocessing procedures highlight a critical gap in patient safety**.** These lapses involved failures to follow recommended reprocessing instructions for critical[1] and semi-critical[2] devices and highlight the need for healthcare facilities to review policies and procedures that protect patients.

The assessment should:

- Ensure appropriate policies and procedures are in place for initial and ongoing training of personnel who reprocess medical devices
- Ensure appropriate and effective systems are in place for ongoing assessment and feedback, including regular audit (monitor and document) of all reprocessing steps including adherence to cleaning, disinfection, sterilization, and device storage procedures
- Ensure comprehensive and appropriate infection control policies and procedures for cleaning, disinfection, and sterilization of reusable medical devices are in place
- Health care administrators should work with their infection prevention personnel and accreditation organizations to ensure that all recommendations are properly implemented to protect patients and personnel.

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[1] **Critical items** (e.g., surgical instruments) are objects used to enter sterile tissue or the vascular system and must be cleaned and sterilized prior to reuse.

[2] **Semi-critical items** (e.g., endoscopes for upper endoscopy and colonoscopy, laryngoscope blades) are objects that contact mucous membranes or non-intact skin and require, at a minimum, cleaning and high-level disinfection prior to reuse.

Additional Information

- Examples of relevant guidance include CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 available at http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf; and guidance from the Association for the Advancement of Medical Instrumentation (AAMI), available at http://www.aami.org/standards/index.aspx.
- Problems with medical device reprocessing should be reported to the FDA's MedWatch Adverse Event Reporting program either online at https://www.accessdata.fda.gov/scripts/medwatch/, by regular mail, or by fax. Download the form at http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm or call 1-800-332-1088 to request a reporting form, then complete and mail to address on the pre-addressed form, or submit by fax to 1-800-FDA-0178. Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (see: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm) should follow the reporting procedures established by their facilities.